



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 3, 2020

Gordon Sargent
Regulatory Manager
AGT Division
Nufarm Americas Inc.
4020 Aerial Center Parkway
Morrisville, NC 27560

Subject: Registration Review Label Mitigation for Metalaxyl and Fludioxonil
Product Name: NUP-13039
EPA Registration Number: 55146-152
Application Dates: 6/26/2018; 9/27/2019
Decision Numbers: 560619; 560620

Dear Mr. Sargent:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Metalaxyl and Fludioxonil Interim Decisions, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

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If you have any questions about this letter, please contact Darius Stanton by phone at 703-347-0433, or via email at Stanton.Darius@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to be "Linda Arrington", with a stylized flourish at the end.

Linda Arrington, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

Enclosure

TEBUCONAZOLE	GROUP	3	FUNGICIDE
METALAXYL	GROUP	4	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

NUP-13039

Seed Treatment

FOR USE ON BARLEY, OATS, TRITICALE, AND WHEAT FOR PROTECTION OF SEEDLINGS AGAINST LISTED SOILBORNE DISEASES

ALTERNATE BRAND NAMES:

SATIVA® M2F RTU

ACTIVE INGREDIENT:

Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester	1.242%
Tebuconazole: Alpha-[2-4(chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-	0.461%
Fludioxonil: 4-(2,2-Difluoro-1,3-benzodioxol-4-yl)-1H-pyrrolle-3-	0.376%

OTHER INGREDIENTS:

	97.921%
TOTAL:	100.000%

Contains:

0.107 pound Metalaxyl per gallon (12.8 grams per liter)
 0.040 pound Tebuconazole per gallon (4.8 grams per liter)
 0.032 pound Fludioxonil per gallon (3.8 grams per liter)

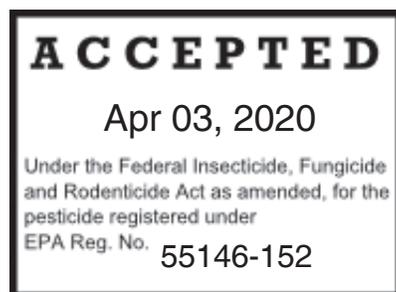
**KEEP OUT OF REACH OF CHILDREN
 CAUTION / PRECAUCIÓN**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
 (If you do not understand the label, find someone to explain it to you in detail.)

**SEE INSIDE BOOKLET FOR FIRST AID, ADDITIONAL PRECAUTIONARY STATEMENTS,
 AND DIRECTIONS FOR USE**

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
 For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 55146-152
 EPA EST. NO. _____



Manufactured For
 NUFARM AMERICAS INC.
 AGT DIVISION
 11901 S. Austin Ave.
 Alsip, IL 60803



Net Contents: _____ Gal. (_____ L)
 [Designation as “NONREFILLABLE” or “REFILLABLE” for containers > 5 GAL]

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • DO NOT induce vomiting unless told to do so by the poison control center or doctor. • DO NOT give anything by mouth to an unconscious person.
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth- to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION / PRECAUCIÓN

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical resistant gloves made out of: barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene, polyvinyl chloride ≥ 14 mils, or viton ≥ 14 mils.

Note: Persons involved in bagging treated seed, sewing or moving bags of treated seed, or cleaning up bagging areas or seed treatment equipment are pesticide handlers and must wear the PPE required on this label for pesticide handlers.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users Should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

PHYSICAL AND CHEMICAL HAZARDS

DO NOT mix or allow coming in contact with oxidizing agents. Hazardous chemical reaction may occur.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish, and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

Groundwater Advisory: Metalaxyl and Tebuconazole are known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Maximum usage when applying both metalaxyl- and mefenoxam-containing products to the same crop within the same season: Do not apply more than the maximum yearly total application rate for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

DO NOT enter or allow worker entry into treated areas during the **restricted-entry interval (REI) of 24 hours**.

Exception: If the seed is treated with the product and the treated seed is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is:

- Coveralls
- Chemical-resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinylchloride (PVC) or Viton.
- Shoes plus socks.

USE RESTRICTIONS

- **DO NOT** use as a planter (hopper) box treatment.
- **DO NOT** use treated seed for feed, food, or oil purposes.
- Store treated seed away from feeds and foodstuffs. **DO NOT** allow children, pets, or livestock to have access to treated seed.
- The maximum yearly total application rate for metalaxyl/mefenoxam for all applications (including seed treatments, foliar applications, soil applications) is 12.3 lb per acre per calendar year. **DO NOT** apply more than 12.3 lb total of the active ingredients, metalaxyl and mefenoxam per acre per calendar year.

RESISTANCE MANAGEMENT RECOMMENDATIONS

NUP-13039 contains tebuconazole, a Group 3 fungicide; metalaxyl, a Group 4 fungicide; and fludioxonil, a Group 12 fungicide. Tebuconazole belongs to the DMI class of chemistry. Metalaxyl belongs to the phenylamide class of chemistry. Fludioxonil belongs to the phenylpyrrole class of chemistry.

Pest populations may contain individuals naturally resistant to active ingredients in NUP-13039 and if used repeatedly in the same fields, then resistant members may eventually dominate the population. Because resistance development cannot be predicted, the use of this product should conform to sound resistance management strategies such as an alternation with insecticides and fungicides of a different mode of action and/or tank mixes established for the crop and use area.

Use should be based on an IPM program that includes field sanitation, scouting, historical information related to pesticide use, and crop rotation. The IPM program should also consider cultural, biological, and other chemical control practices.

Nufarm encourages responsible product stewardship to ensure effective long term control of the fungal diseases on this label.

For additional information on Fungicide Resistance Management:

- Contact Nufarm Americas Inc representatives at 1-800-345-3330
- Contact your local extension specialist or certified crop advisor.
- Visit the Fungicide Resistance Action Committee (FRAC) at <http://www.frac.info>

SEED TREATMENT

This product is a mixture of the fungicides Metalaxyl, Tebuconazole, and Fludioxonil. When used on listed crops, the fungicide mixture in this product provides more consistent control when disease pressure is high. This product aids in the control or suppression of the following seed, seedling and soilborne diseases on seed and young seedlings of Barley, Oats, Triticale, and Wheat.

CROP	INSECT / DISEASE CONTROL	RATE
Barley Oats Triticale Wheat	Seed decay caused by <i>Aspergillus</i> , <i>Penicillium</i> , and other species. Early season disease control of <i>Pythium</i> damping-off, Stinking smut, Flag smut, Loose smut, Early season <i>Septoria</i> disease complex, Early season <i>Rhizoctonia</i> root rot, Early season common root rot, Early season <i>Fusarium</i> foot rot, Early season suppression of powdery mildew and early season suppression of wheat leaf rust.	3.4 to 5.0 fluid ounces per 100 pounds of seed
<p>APPLICATION DIRECTIONS: Apply prior to planting as a slurry treatment. This product is to be used in liquid or slurry treaters only. Mix thoroughly before use or use entire container at one time. Ensure thorough coverage. All tank mixes should be pre-tested to determine physical compatibility between formulations. Follow the most restrictive precautions and limitations on the labeling of all products used in mixtures.</p> <p>In California: For use in commercial seed treating establishments only. Not allowed for “on-farm” use.</p>		

SEED BAG LABELING REQUIREMENTS

Seed commercially treated with this product must be labeled in accordance with all applicable requirements of the Federal Seed Act. The user of this product is responsible for ensuring that the seed bag meets all requirements under the Federal Seed Act.

THE FEDERAL SEED ACT REQUIRES THAT BAGS CONTAINING TREATED SEEDS BE LABELED WITH THE FOLLOWING STATEMENTS:

- This seed has been treated with NUP-13039 Seed Treatment (metalaxyl, tebuconazole, fludioxonil).
- **DO NOT** use for feed, food, or oil purposes.

THE US ENVIRONMENTAL PROTECTION AGENCY REQUIRES THE FOLLOWING STATEMENTS ON BAGS CONTAINING SEEDS TREATED WITH NUP-13039 Seed Treatment (metalaxyl, tebuconazole, fludioxonil):

- Store treated seed away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants and chemical resistant gloves when handling treated seed.
- **DO NOT** allow children, pets, or livestock to have access to treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- Excess or leftover seed may be double-sown around the headland or buried away from bodies of water in accordance with local requirements.
- **DO NOT** contaminate water bodies when disposing of planting equipment wash water.
- **DO NOT** graze, harvest for forage, or feed livestock on treated areas for 31 days after planting.
- Dispose of seed packaging in accordance with local requirements.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticides remain in the ethanol by-products that are used in agronomic practice.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool place, **DO NOT** store in direct sunlight. Protect from freezing temperatures.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

[Note to Reviewer: The following statement will be included on all Final Printed Labels bearing multiple Container Handling statements] **NOTE:** This product is available in multiple containers. Refer to the Net Contents section of this products labeling for the applicable “Nonrefillable” or “Refillable” designation. Follow the container disposal [handling] instructions below that apply to your container type / size.”

[Nonrefillable Containers 5 Gallons or Less]

Nonrefillable container. DO NOT reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke.

[Nonrefillable containers larger than 5 gallons]

Nonrefillable container. DO NOT reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Offer for recycling if available. If recycling or reconditioning is not available, puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. **Triple rinse as follows:** Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

[Refillable containers larger than 5 gallons]

Refillable container. Refill this container with pesticide only. **DO NOT** reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. For final disposal, offer for recycling if available. If recycling or reconditioning is not available, puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV061218)

[Sativa is a registered trademark of Nufarm Americas Inc.]

All other trademarks are the property of their respective owners.

[NOT INCLUDED IN FINAL PRINTED LABELING]

LABEL HISTORY

File Name	Revision Mark	Comment
055146-00xxx.20141105.DRAFT (NUP-13039)	RV110514	Section 3- Draft Label
055146-00RLE.20150204.DRAFT (NUP-13039)	RV020415	Updated Phys/Chem Hazard Stmt as per EPA memo 1/30/15
055146-00RLE.20150512.DRAFT (NUP-13039)	RV051215	Revised as per EPA request 5/12/15
055146-00RLE.20150515.DRAFT (NUP-13039)	RV051515	Additional Revisions requested by EPA
055146-00152.20150520.MASTER	RV052015	EPA Approval
055146-00152.20150528.DRAFT	RV052815	Notification of Alternate Brand Name Change
055146-00152.20150701.MASTER	RV070115	EPA Approval
055146-00152.20180612.DRAFT	RV061218	Update for Metalaxyl PID
055146-00152.20190601.DRAFT	RV_____	Update for Metalaxyl PID